IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 8 CASES ON ATTACHED EXHIBIT A	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF DEFENSE EXPERT MILES MURPHY

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Plaintiffs respectfully request that this Court exclude or limit certain expert testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Miles Murphy M.D. ("Dr. Murphy"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Miles Murphy is a Urogynecologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge his qualifications as such.[1] Dr. Murphy's general report relating to Ethicon's TVT and TVT-O devices purportedly sets forth opinions on all liability issues with regard to those devices, including failure to warn and design defect, which also includes opinions on the material properties of polypropylene mesh. However, Dr. Murphy never directly states his specific opinions. Nor does he address the objective standards or criteria in forming his opinions and, thus, follows no scientific methodology that can be discerned.

Dr. Murphy's general report relating to Ethicon's Prolift device actually sets forth opinions regarding the safety and efficacy of the Prolift, the pre-launch studies, and the adequacy of the warnings and brochures.[2] However, Dr. Murphy's deposition shows that those opinions are all net opinions. It is well understood that Dr. Murphy's experience in the field of Urogynecology does not render all of his opinions admissible. The admission of Dr. Murphy's unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury.[3] As this Court previously noted,"[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that

[1] Wave 8 - TVT and TVT-O General Report of Miles Murphy, MD at p. 1 (attached as Ex. B); *see also* Curriculum Vitae of Dr. Murphy (attached as Ex. C).
[2] Wave 8 – Prolift General Report of Miles Murphy, MD (attached as Ex. D).
[3] *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.') (citing *Daubert*, 509 U.S. at 596).

the expert 'has reliably applied the principles and methods to the facts of this case.'"[4] Accordingly, Dr. Murphy should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.[5] The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge.[6]

ARGUMENT

I. Dr. Murphy's General Opinions on Adequacy of Warnings Regarding Ethicon's Prolift Device Should Be Precluded or Limited

In his November 30, 2012, deposition, Dr. Murphy admitted that he only relied on his own personal standards to form his opinions with regard to Ethicon's Prolift device. For example, with regard to the warnings in the IFU and Patient Brochure:

> Q. The standard you just gave me of what you think should be in an IFU, is that just your own personal standard?
>
> A. That was my opinion of what makes sense to be in an IFU.
>
> Q. That's your own personal opinion not based on any other information you've read or seen, correct?
>
> A. Correct.
>
> Q. It's your own personal viewpoint your own personal standard, correct?

[4] *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).
[5] *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).
[6] *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

A. Yes.

Q. With regard to what would need to be included in the patient brochure with regard to risks and benefits to the extent you've drawn any opinions in your report on that again is that based on your own personal standard your own personal opinion?

A. I do not -- I think the answer is yes because I don't know any sort of legal guidelines by which patient brochures are supposed to be produced.

Q. And do you have any information you can share with me now that you gleaned from any Ethicon documents or testimony where you saw what Ethicon thought the standards were to determine whether or not a risk or a benefit would need to be described and how it should be described in a patient brochure?

A. I don't recall seeing any standards that they refer to.

Q. Did you see any testimony in any deposition that you are relying on as you sit here now with regard to what needs to be included in an IFU?

A. I do not recall seeing anything like that.

Q. So again with regard to the IFU and the contents of the IFU whatever opinion yon are drawing is just based on your own personal opinion not based on what any other standards may be or what anyone else might think, correct?

A. Right it's my expert opinion not based on outside information.[7]

This is the very definition of a net opinion as Dr. Murphy solely relied on his own "personal opinion" and no outside information or standards. Therefore, any opinion Dr. Murphy may have on the adequacy of the Prolift IFU would amount only to pure speculation. The law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent.[8] Accordingly, Dr. Murphy should be barred from rendering any opinions on the adequacy of the IFUs, patient brochures or other marketing materials for the Prolift device.

[7] Miles Murphy, M.D. 11/30/2012 Dep. Tr. at 350:2-351:14, attached as Ex. E.

[8] *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

II. Dr. Murphy Should be Precluded from Rendering any Opinions on Whether Ethicon Acted Reasonably or Met the Standard of Care with Regards to Ethicon's Prolift Device

Dr. Murphy should be barred from rendering any opinions as to whether Ethicon acted reasonably or met the standard of care because he acknowledged in his November 30, 2012, deposition that he has no idea as to what Ethicon knew and thought as to the risks of the Prolift:

> Q. Do you know as you sit here now based on whatever you reviewed what the potential risks of the Pro lift were from the perspective of what medical affairs in Ethicon knew?
>
> A. I do not know what medical -- what that group knew.
>
> Q. Would you assume that Ethicon medical affairs would have more information about the overall potential risks of the Prolift than you would have?
>
> A. I don't know if they would know more. I think they would know probably most that I would.
>
> Q. As you sit here now you don't know what risks Ethicon medical affairs has testified to knowing about at different points in time, correct?
>
> A. I can't recall any testimony that I saw regarding that.
>
> Q. You certainly didn't talk about that subject in your reports, correct?
>
> A. Correct.[9]
>
> * * *
>
> Q. Am I correct that you reviewed very little by way of documents indicating what the people within medical affairs at Ethicon thought at any particular point in time?
>
> A. What I'm saying is I got stacks of documents within the last two weeks that were about 2 feet high and I have only gotten through a small percentage of that.
>
> Q. As you sit here now you don't feel that you have a good understanding of what the people in medical affairs at Ethicon thought with regard to mesh shrinkage, erosion or other topics?

[9] Ex. E at 354:2-355:4.

A. If you read my report I don't think anywhere do I mention what people in medical affairs at Gynecare knew or didn't know.[10]

Based on the lack of facts to support his opinion, Dr. Murphy cannot opine regarding whether Ethicon acted reasonably or met the standard of care.

III. Dr. Murphy's Other Opinions Regarding Ethicon's Prolift Device Should be Precluded or Limited

Dr. Murphy also acknowledged in his November 30, 2012, deposition that he has no opinions on numerous issues which were purportedly addressed in his report. Accordingly, he should be precluded from offering opinions on the following subjects:

1. The internal pre-market design and evaluation process (DDSA, FMEA) conducted by Ethicon for the Prolift.[11]

2. The French and US TVM Studies, including:

   - He does not know how Ethicon utilized or relied on the TVM Studies.
   - Whether or to what extent there were errors with the POP-Q measurements which were used to determine whether the patients had prolapse recurrences
     .
   - Why differences in exposure rates existed from hospital to hospital.
   - He has no opinion on whether or to what extent the exposure rates were accurately counted or undercounted.
   - Whether the exposure rates or recurrence rates reported in the published articles actually reflects what was recorded in the underlying case report forms, the SAS database, or anything like that. "I did not have any access to the primary data, only what was published."[12]

3. The Gynemesh PS Study, including:

   - He does not know whether or to what extent Ethicon relied on or utilized the Gynemesh PS study.

[10] Ex. E at 476:1-15.
[11] *Id*. at 103:25-104:20.
[12] *Id*. at 106:5-110:3.

- He has never reviewed the underlying Gynemesh PS data, for example the patient report forms, and has no ability to say whether the reported results are consistent with the data that was collected.[13]

4. Whether or not it was reasonable for Ethicon to decide that the Prolift was safe and effective to be marketed, as he has no idea what was relied on.[14]

IV. Dr. Murphy Should Not be Allowed to Rely on Materials that he Did Not Read or Rely on to Write his Prolift Report

Dr. Murphy's expert report includes an extensive list of reliance materials, yet he admitted during his deposition that he has **not** reviewed many of the materials and does not know what most contain. Accordingly, if Dr. Murphy is permitted to testify to any extent, he should be precluded from testifying with regard to, or relying on, anything other than the bibliography to his report.

Specifically, he admitted:

1. He did not read the entire deposition transcripts and exhibits.

2. He does not recall how many pages of the transcript he read.

3. The list of "Additional Materials" was included so that he could say he listed them in case he wanted to mention them at trial.

4. He did not rely on all the “Additional Materials.”

5. He read part of Anne Weber's report, but none of the other plaintiff expert reports when he authored his report.

6. He would be unable to go through the list of Additional Materials and identify the things he looked at versus the things that were listed in case he wanted to reference them later.

7. The items referenced in the bibliography is the universe of items he thought were important when he drafted the report, and thus were referenced.

8. Internal Ethicon documents were only listed because they were given to him in case he would need to reference them when he testified.

[13] Ex. E at 110:4-112;19.
[14] *Id*. at 112:20-115:13.

9. He never asked what internal documents had been produced by Ethicon on discovery, and he did not request any.

10. With regard to the list of materials at the end of the supplemental report, he could not tell what some of the materials said, and he only read the depositions of plaintiff experts Tom Margolis, M.D. and Daniel Elliott, M.D. in their entirety. He read 10% of his partner Vincent Lucente's transcript.

11. He read less than 20% of all the materials listed at the end of his supplemental report.[15]

Since he did not review the materials set forth above -- and he was not questioned about them during his November 30, 2012, deposition -- Dr. Murphy should be precluded from relying on any of them at any potential trial without Plaintiffs having the opportunity to re-depose him on these materials.

V. Dr. Murphy's General Opinions on Adequacy of Warnings Regarding Ethicon's TVT and TVT-O Devices Should Be Precluded or Limited

As discussed in the introduction above, Dr. Murphy's report does not specifically address the adequacy of the Ethicon TVT and TVT-O device warnings, including the Instructions for Use ("IFU") for either device.[16] He nonetheless attempts to offer his more specific opinions during his October 9, 2018, deposition. However, Dr. Murphy does not possess the experience, training, and knowledge with regard to drafting IFUs which makes him unqualified to offer such opinions. First, Dr. Murphy has never drafted an IFU.[17] Nor, has he provided input to a medical device company on what information needs to be included in an IFU.[18] Second, Dr. Murphy once again admitted that he only relied on his own personal standards to form his opinions.[19]

[15] Ex. E at 17:16-29:21; 133:15-134:9.
[16] *See* Ex. B generally - Dr. Murphy's report does not address any specific opinions regarding Ethicon's TVT and TVT-O devices and, thus, does not describe any standards or methodology that would be able to support any conclusions he seeks to make on the matter. Dr. Murphy's report merely makes sweeping, general opinions regarding the history of treatment of stress urinary incontinence, the development of the TVT and TVT-O devices, and summary conclusions regarding the TVT and TVT-O comparative and long-term data.
[17] *See* Miles Murphy, M.D. 10/9/2018 Dep. Tr. at 203;7-204:2 (attached as Ex. F).
[18] Ex. F at 202:13-203:6.
[19] *Id*. at 204:17-205:6.

Therefore, any opinion Dr. Murphy may have on the adequacy of the TVT and TVT-O IFUs would again amount only to pure speculation. Dr. Murphy should not be allowed to backdoor into evidence his improper and unsupported general opinions regarding Ethicon's TVT and TVT-O devices because it would be impossible to evaluate the reliability of any such conclusions. Consequently, Dr. Murphy's opinions on the adequacy of Ethicon's TVT and TVT-O warnings are unreliable and should be precluded.

VI. Dr. Murphy's General Opinions on the Design and Material Properties of the TVT and TVT-O Devices Should Be Precluded or Limited.

Again, Dr. Murphy's report does not specifically address the adequacy of the design and material properties of Ethicon's TVT and TVT-O devices. Dr. Murphy is a board certified Urogynecologist with a practice focused on urology and pelvic floor medicine.[20] However, he does not have any specialized education specifically related to the design or material properties of polypropylene mesh devices.[21] Despite not having any formal education in materials engineering, chemical engineering, or polymer chemistry, he arbitrarily offers opinions regarding the design and the material properties of Ethicon's TVT and TVT-O devices. Specifically, he opines that polypropylene does not degrade[22] and that any fraying or particle loss of the polypropylene mesh would not have any clinical significance for patients.[23] Dr. Murphy has never performed any bench research on polypropylene, nor has he published any articles related to polypropylene mesh and degradation in the human body.[24] He has never even examined explanted mesh under an electron microscope.[25] Dr. Murphy simply does not have the requisite

[20] *See* Ex. B; *see also* Ex. C.
[21] *See* Ex. F at 110:8-13; 253:9-11; 254:14-21.
[22] *Id*. at 112:21-117:2.
[23] *Id*. at 133:24-134:23; 250:1-14.
[24] Ex. F at 110:14-113:12.
[25] *Id*. at 107:4-108:13.

experience to proffer these opinions. Thus, his opinions amount to nothing more than assumptions, and therefore are unreliable under *Daubert*.[26]

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from Dr. Miles Murphy, regarding (a) adequacy of warnings regarding Ethicon's Prolift device (b) whether Ethicon acted reasonably or met the standard of care with regards to its Prolift device (c) whether Ethicon's Prolift device should be precluded or limited (d) the adequacy of the TVT warnings and (d) opinions regarding the design and scientific properties of the TVT mesh device. Plaintiffs further request all other relief to which they are entitled.

Dated: October 18, 2018

Respectfully submitted,

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[26] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 18, 2018, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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